

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: 10/751,702 Confirmation No.: 1142  
Applicant(s): Tuomanen *et al.*  
Filed: January 5, 2004  
Art Unit: 1645  
Examiner: N. Minnifield  
Title: A POLYPEPTIDE COMPRISING THE AMINO ACID OF AN N-TERMINAL CHOLINE BINDING PROTEIN A TRUNCATE, A VACCINE DERIVED THEREFROM AND USES THEREOF

Docket No.: 044158/273011  
Customer No.: 29312

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RULE 37 C.F.R. § 1.132 DECLARATION  
Of  
DR. ELAINE INGRID TUOMANEN**

Sir:

I, Dr. Elaine Tuomanen, do hereby declare and say as follows:

1. I am skilled in the art of the field of the invention. I am presently the Director of the Children's Infection Defense Center of St Jude Children's Research Hospital, in Memphis, TN working in the area of pneumococcal vaccines. I received a degree of Doctor of Medicine (MD) and a degree of Master of Surgery (CM) from McGill University in 1977, and a degree of Bachelor of Science in Biochemistry from McGill University in 1973.
  
2. I have read and understood the Office Action in the above case dated January 25, 2008 and the Advisory Action dated May 21, 2008.

3. SEQ ID NO:4 is 106 amino acids in length and is an N-terminal fragment of the Choline Binding Protein A from serotype 4. The data shown below employs a peptide, referred to herein as SEQ4-A, that is identical to that of SEQ ID NO:4 except that it lacks the first 2 N-terminal amino acids.

4. Mice (10 per group repeated X 2) were immunized with albumin (BSA = negative control) or 200 µg of the SEQ4-A polypeptide at 0, 14 and 28 days. One week later they were challenged with 107 cfu of T4 pneumococci into the nose. Bacteria in the blood and nasal wash were enumerated at 96 and 48 h respectively.

5. Employing the method described at point #4, we found that immunization with SEQ4-A significantly decreased the bacteria per mouse. See, Figure 1.

6. We further studied the survival of mice that were immunized with SEQ4-A. Employing the methods outlined above in point #4, the mice that were immunized with SEQ4-A were challenged with pneumococci of different serotypes. The percentage of survival at day 5 post-challenge is summarized in Table 1. Statistically significant protection was seen for serotypes 2 and 6B.

Table 1

<u>Immunogen</u>	<u>Serotype</u>		
	<u>2</u>	<u>6B</u>	<u>19F</u>
SEQ4-A	90	50	30
BSA control	30	20	20

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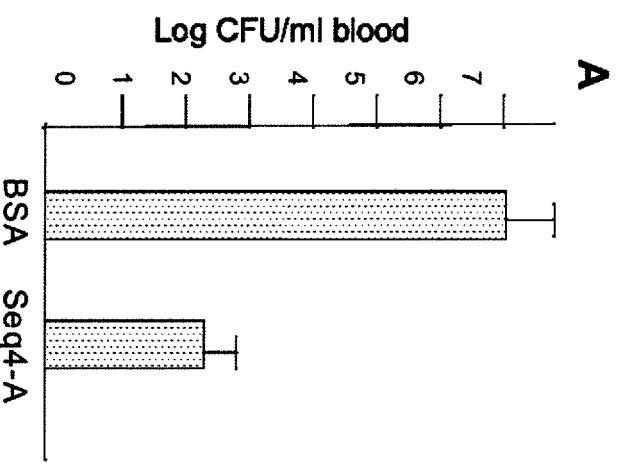
7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: July 11/2008

By:   
Dr. Elaine Tuomanen

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**Blood bacterial load at 96 h**



**Colonization of the nose at 48 h**

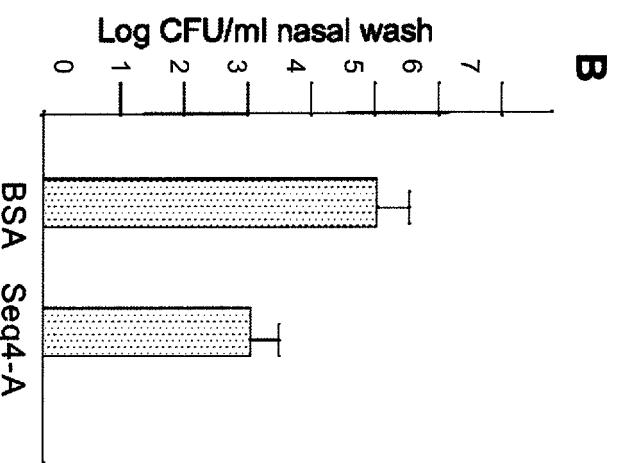


Figure 1